UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: Nexium (Esomeprazole Magnesium) Antitrust Litigation This Document Relates to: All Actions	MDL No. 2409 Civil Action No. 1:12-md-02409-WGY

MEMORANDUM IN SUPPORT OF ASTRAZENECA DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON ALL CLAIMS ARISING FROM ASTRAZENECA'S SETTLEMENTS WITH TEVA AND DRL

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Plaintiffs' antitrust claims concerning AstraZeneca's settlements with Teva and DRL require Plaintiffs to establish, *inter alia*, that the settlements involved a "large, unjustified reverse payment." *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013). With discovery now complete, it is clear that these claims are based on conclusory allegations unsupported by competent evidence and on legal theories rejected by the Supreme Court in *Actavis*. Because there is no genuine issue for trial on critical elements of Plaintiffs' claims, the Court should grant summary judgment on all claims arising from or predicated on the Teva and DRL settlements.[1]

Plaintiffs' contention that AstraZeneca's settlement with Teva of a separate patent suit involving Prilosec amounts to a "reverse payment" fails under *Actavis*. Plaintiffs have no admissible evidence to support their theory that the settlement of the Prilosec litigation—in which *Teva paid AstraZeneca* [redacted]—involved a reverse payment because AstraZeneca allegedly could have won greater damages if it had litigated the case to conclusion. Plaintiffs fail to proffer any admissible evidence that the value of AstraZeneca's claim against Teva exceeded [redacted] plus the attorney's fees and costs that were saved by virtue of the settlement. Accordingly, Plaintiffs have no competent evidence that the Prilosec settlement involved any payment from AstraZeneca to Teva, let alone a "large, unjustified reverse payment." *Id.*

Similarly, Plaintiffs' claim that AstraZeneca's settlement with DRL of the Accolate litigation involved a reverse payment cannot be squared with *Actavis*. In that settlement, AstraZeneca paid nothing to DRL to resolve a patent suit that AstraZeneca had lost on summary judgment. Plaintiffs and their army of experts offer no evidence whatsoever of the value of the

[1] This memorandum is filed on behalf of Defendants AstraZeneca LP, AstraZeneca AB and Atkiebolaget Hässle (collectively, "AstraZeneca").

supposed payment made by AstraZeneca to DRL. Under these circumstances, they cannot possibly prove that any alleged reverse payment was large and unjustified, as *Actavis* requires.

Finally, AstraZeneca's settlements with Teva and DRL do not involve reverse payments as a matter of law. Under *Actavis*, a reverse payment settlement is one in which the "settlement *requires the patentee to pay the alleged infringer*, rather than the other way around." *Id.* at 2227 (emphasis added). The Supreme Court made clear in *Actavis* that the conventional compromise of a damages claim in which the plaintiffs receives less than the full amount of its claim is not a reverse payment and does not give rise to antitrust concerns. *Id.* at 2233. The Teva Prilosec settlement and the DRL Accolate settlement involved either a payment from the defendant to AstraZeneca of a compromise sum (Teva) or no payment at all (DRL). Those "traditional" settlements, *id.* at 2233, which take "commonplace forms," *id.*, do not, as a matter of law, involve reverse payments subject to antitrust scrutiny. *Id.*[2]

ARGUMENT

I. PLAINTIFFS HAVE NO ADMISSIBLE EVIDENCE THAT ASTRAZENECA'S SETTLEMENTS WITH TEVA AND DRL INVOLVED LARGE, UNJUSTIFIED REVERSE PAYMENTS.

The Teva and DRL settlements are not subject to antitrust scrutiny under *Actavis* unless Plaintiffs establish they involved a "large, unjustified reverse payment." 133 S. Ct. at 2237. Plaintiffs cannot meet their burden of proof on this essential element of their claims.[3]

[2] AstraZeneca recognizes that the Court addressed this latter argument in its opinion concerning Defendants' motions to dismiss. *See* Dkt. No. 352 at 40-43. The Court, however, did not have the benefit of any briefing from the parties concerning *Actavis* at the time it rendered that opinion, and thus this point of law should be considered at the summary judgment stage with the benefit of full briefing.

[3] State antitrust laws must be interpreted in harmony with federal antitrust law. *See* Dkt. No. 156 at 2 n.2 (collecting authorities). The Indirect Purchasers' complaint contains the same allegations as the Direct Purchaser's complaint and asserts substantively identical state law claims.

"The office of a summary judgment motion is to test the sufficiency of the opposing party's evidence. Thus, a party moving for summary judgment is free to assert that the record before the court fails to make out a trial-worthy question of material fact as to a dispositive issue. Once the movant takes such a position, it is the burden of the nonmoving party to proffer facts sufficient to rebut the movant's assertions." *Nansamba v. N. Shore Med. Ctr., Inc.*, 727 F.3d 33, 40 (1st Cir. 2013). "Where, as here, the nonmovants have the burden of proof on the dispositive issue, they must point to specific facts sufficient to deflect the swing of the summary judgment scythe." *Ahern v. Shinseki*, 629 F.3d 49, 54 (1st Cir. 2010) (quotation omitted). "[C]onclusory and unsubstantiated allegations are insufficient to meet [Plaintiffs'] burden" at the summary judgment stage. *Lewis v. Whitman-Hanson Regional School Dist.*, 843 F. Supp. 2d 182, 190-91 (D. Mass. 2012). Summary judgment is warranted here because Plaintiffs have no trial-worthy evidence to support their claims that the Prilosec and Accolate settlements involved large unjustified reverse payments.

A. Plaintiffs' Claim that AstraZeneca's Settlement of the Prilosec Litigation with Teva Involved a Reverse Payment Is Not Based on Competent Evidence.

At the same time that AstraZeneca and Teva settled the Nexium litigation, they also settled separate patent litigation involving the drug Prilosec. SUF ¶¶ 2, 9.[4] Teva paid [redacted] to AstraZeneca to settle the Prilosec litigation. SUF ¶ 9. Yet Plaintiffs characterize that settlement as a reverse payment, claiming that it "absolv[ed] Teva[] of damages for a payment well below what AstraZeneca could have reasonably expected had it pursued the litigation." *See* Ex. 52 ((Excerpts from Report of Richard G. Frank and Thomas G. McGuire) ¶ 188. Plaintiffs'

[4] All references herein to "SUF" are to the Statement of Undisputed Facts on all Claims Arising from AstraZeneca's Settlement with Ranbaxy, filed herewith. All exhibits referenced herein are exhibits to the Declaration of James Weingarten, filed herewith.

claim fails because they have no admissible evidence that AstraZeneca would have won a judgment against Teva in excess of [redacted] (plus saved litigation costs) if it had not settled the Prilosec litigation. In addition, as discussed in Part II, Plaintiffs are wrong as a matter of law in claiming that AstraZeneca's compromise of its damages claim against Teva in the Prilosec litigation could be a "reverse payment" under *Actavis*.

The only putative evidence Plaintiffs present on the valuation of AstraZeneca's damages claim against Teva in the Prilosec litigation is the proposed expert testimony of Professor Thomas McGuire. SUF ¶ 12.[5] Professor McGuire fails to provide any competent evidence that AstraZeneca would have won a damages award against Teva in excess of [redacted] plus saved litigation costs.

Professor McGuire conceded in his initial expert report that, because Teva was the fifth generic entrant, AstraZeneca's damages claim against Teva in the Prilosec litigation would have been based on a reasonably royalty.[6] He opined that, if there had not been a settlement,

[5] Plaintiffs' other experts failed to conduct any analysis of the value of AstraZeneca's claims against Teva in the Prilosec Litigation. Class Plaintiffs' expert Shashank Upadhye made no attempt "to quantify" the alleged reverse payment to Teva. SUF ¶ 13. Although his report makes the wholly conclusory assertion that damages in the Prilosec Litigation "were likely in the tens of millions of dollars," *id.*, he admitted in his deposition that this opinion was merely his "assumption and characterization of what AstraZeneca could have likely recovered." *Id.* Similarly, Retailer Plaintiffs' expert Professor John Thomas makes the conclusory assertion that Teva "faced significant liability resulting from its infringing generic Prilosec sales." SUF ¶ 14. But he admitted in his deposition that he made no attempt to quantify that potential liability. *Id.* "Where an expert presents nothing but conclusions . . . such testimony will be insufficient to defeat a motion for summary judgment." *Control Res., Inc. v. Delta Elecs., Inc.*, 133 F. Supp. 2d 121, 133 (D. Mass. 2001) (quotations omitted). Retailer Plaintiffs' expert Keith Leffler's report contains the conclusory assertion that the settlement with Teva involved an "effective payment" "in the form of forgiveness of potential liability." SUF 15. At deposition, however, Dr. Leffler testified that he is not offering any opinion that the settlement involved an effective payment. *Id.*

[6] *See* SUF 17 ("At the time of Teva's launch [of generic omeprazole], five other generic manufacturers were selling omeprazole in the U.S. In calculating the amount that Teva would (continued…)

AstraZeneca would have obtained a "royalty fee" of $34.4 million against Teva. SUF ¶ 16.[7] After subtracting avoided litigation costs and the [redacted] paid by Teva in the settlement, Professor McGuire opined that "the payment from AstraZeneca to Teva/Impax was at least $24.4 million." *Id.*[8]

At deposition, however, Professor McGuire admitted that his report does *not* attempt to estimate the reasonable royalty rate damages that AstraZeneca could have recovered in the Prilosec litigation. Remarkably, Professor McGuire conceded at his deposition that, even though his expert report states that AstraZeneca's potential damages against Teva should be measured by a reasonable royalty analysis (Ex. 52 ¶ 190), and Paragraph 192 of his report purports to calculate a reasonable royalty, Paragraph 192 is not in fact a "reasonable royalty" analysis at all. SUF ¶ 18 & Ex. 53 (McGuire Dep.) at 197-98 ("Well, I don't consider this to have been a reasonable royalty."); *id.* at 198 ("It's something else. "); *id.* at 199 ("This is not an estimate of a reasonable royalty."); *id.* at 279 ("[P]robably if I were rewriting it [¶ 192] now, I would just get rid of the word royalty, which I think is a little misleading there.").

Professor McGuire admitted in his deposition that he made no attempt to calculate the reasonable royalty damages that AstraZeneca could have won against Teva in the Prilosec Litigation. SUF ¶ 18. He asserted that his use of the word "royalty" in his report "is a typo," and that the $34.4 million figure in his report merely represents a "fee" that Teva and

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have reasonably owed AstraZeneca [absent the settlement] it is important to take the existence of other generic entrants into consideration. It is likely that, if Teva had not entered, buyers of Teva's generic product would have purchased from one of the other five generics and not from the brand [AstraZeneca]. As such, it is reasonable, and certainly conservative to evaluate the Prilosec agreement based on a reasonable royalty.").

[7] Professor McGuire originally submitted a report with now-withdrawn expert Richard Frank. [redacted]

AstraZeneca *might* have negotiated with Teva. SUF ¶ 19. Professor McGuire candidly acknowledged that this "fee" has nothing to do with the damages that AstraZeneca could have claimed against Teva because it not the product of a reasonable royalty analysis using the factors enumerated in *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970). *Id.* He admitted that he made no attempt to apply the well-established *Georgia-Pacific* factors. SUF ¶ 20 (Q. "And did you make any attempt to apply the Georgia-Pacific factors in this case?" A. "No.").[9] Professor McGuire's opinion— which has nothing to do with the calculation of reasonable royalty damages—is not based on a reliable methodology. It makes no attempt to apply the required *Georgia Pacific* factors and is not competent evidence of the value of AstraZeneca's damages claim against Teva in the Prilosec litigation.[10]

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[9] Professor McGuire's report included the conclusory assertion that AstraZeneca might have been able to negotiate a "fee" of 80% of Teva's alleged total profits because AstraZeneca received an [redacted] royalty fee "in multiple distribution agreements with Ranbaxy." SUF ¶ 16. But, as he admitted in his deposition, this is not a reasonable royalty analysis. SUF ¶¶ 18-20. Distribution agreements (which involve AstraZeneca manufacturing the product and a generic company only distributing it) are not a relevant reference point for reasonable royalty damages, which must be based on the royalties AstraZeneca would have received from a hypothetical non-exclusive *license* that would allow Teva to manufacture and distribute the product itself. *See Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1554 (Fed. Cir. 1995) ("The hypothetical negotiation requires the court to envision the terms of a licensing agreement reached as the result of a supposed meeting between the patentee and the infringer at the time infringement began."). A reasonable royalty analysis must be based on other licenses that are "commensurate with what the defendant has appropriated. If not, a prevailing plaintiff would be free to inflate the reasonable royalty analysis with conveniently selected licenses without an economic or other link to the technology in question." *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 872 (Fed. Cir. 2010) (per curiam). An exclusive distribution agreement involving a product manufactured by AstraZeneca clearly is not commensurate with a bare non-exclusive patent license. SUF ¶ 21. Indeed, Professor McGuire admitted that he is not aware of any patent infringement case in which damages were measured by reference to the profit sharing rate in distribution agreements for authorized generics. SUF ¶ 19.

[10] *See Ruffin v. Shaw Indus.*, 149 F.3d 294, 300 (4th Cir. 1998) ("Dr. Anderson's testimony is not admissible under F.R.E. 702 and the Supreme Court's 'reliability' prong established in *Daubert*. Thus, because Dr. Anderson's testimony would not be admissible in evidence pursuant to Fed. R. Civ. P. 56(e), her affidavits and deposition testimony cannot be considered in determining (continued…)

Further, to the extent Plaintiffs speculate that AstraZeneca could have won unspecified enhanced damages against Teva in the Prilosec litigation based on willful infringement, Plaintiffs offer no competent evidence in support of that claim either. Plaintiffs offer nothing but speculation in support of their contention concerning enhanced damages and fail to make any attempt to quantify any potential enhanced damages award.[11]

In sum, there is no competent evidentiary basis for Plaintiffs' claim that the Prilosec settlement amounts to a "large, unjustified," *Actavis,* 133 S. Ct. at 2237, payment. Because Plaintiffs have no admissible evidence to support their contention that AstraZeneca would have won a damages award against Teva in excess of the [redacted] settlement plus saved litigation costs, the Court should grant summary judgment on all claims arising from AstraZeneca's settlements with Teva.[12]

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defendants' summary judgment motion."); *Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1448 (D.V.I. 1994) (granting summary judgment for defendant where the "opinions of each of plaintiff's expert witnesses are inadmissible under Fed. R. Evid. 702, 703 and 403, and are, in any event, insufficient to sustain a jury verdict in plaintiff's favor").

[11] Mr. Upadhye observes in his report that "AstraZeneca also sought enhanced damages (such as triple damages), costs, and fees, asserting that Teva's infringement was reckless and willful. Accordingly, AstraZeneca stood to earn multiples of the [redacted] it ultimately agreed to accept." SUF ¶ 25. Mr. Upadhye makes no attempt, however, to opine about the likelihood that AstraZeneca would have won any enhanced damages against Teva or to quantify the amount of any such damages. *Id.* The undisputed factual record is that AstraZeneca was unsuccessful in asserting claims for willful infringement against Apotex, the other generic company that was found to have infringed the Prilosec patents in the same trial in which the finding of infringement was entered for the product sold by Teva. *See AstraZeneca AB v. Apotex Corp.*, No. 01 Civ. 9351, M-21-81, 2010 WL 2541180, at *5-6 (S.D.N.Y. June 9, 2010). Moreover, Teva received an opinion letter from counsel prior to its first at-risk sale stating that its product did not infringe AstraZeneca's patents, SUF ¶ 26; such an opinion letter can prevent the imposition of enhanced damages for willful infringement. *See Studiengesellschaft Kohle v. Dart Indus., Inc.*, 862 F.2d 1564, 1579 (Fed. Cir. 1988).

[12] Indeed, although the Court need not reach this issue to grant summary judgment for AstraZeneca, the record reflects that the [redacted] Teva agreed to pay AstraZeneca in the Prilosec Litigation was entirely reasonable—and certainly not a large, unjustified payment by (continued…)

B. Plaintiffs' Claim That AstraZeneca's Settlement of the Accolate Litigation with DRL Involved a Reverse Payment Is Based on Inadmissible Speculation.

At the same time that AstraZeneca settled the Nexium litigation with DRL, it settled separate litigation against DRL related to the drug Accolate. In the settlement, AstraZeneca agreed to dismiss its pending appeal from an adverse summary judgment decision and DRL released its claim against AstraZeneca for attorney's fees and expenses. SUF ¶ 35. AstraZeneca did not agree to make any payment to DRL. *Id.*

Plaintiffs claim that the Accolate settlement involved a reverse payment because DRL had a contingent liability that AstraZeneca forgave by dismissing its pending appeal. Dkt. No. 131 ¶¶ 133-34. According to Plaintiffs, AstraZeneca effectively "paid" DRL by forgiving DRL's "outstanding infringement liability" in the Accolate Litigation. Dkt. 167 at 5.

AstraZeneca to Teva. Teva's net sales of omeprazole [redacted]. SUF ¶ 25. The [redacted] payment amounts to a 22 percent royalty on Teva's infringing sales. As reflected in the analyses done by Defendants' experts, such a royalty rate was clearly reasonable in light of the following undisputed facts: (1) Teva was the fifth generic entrant at the time it began sales of omeprazole in September 2004 (SUF ¶ 8); (2) the first generic launched in December 2002, nearly two years earlier (*id.*); (3) three generic entrants that preceded Teva were found not to infringe AstraZeneca's patents (*id.*); (4) Teva would be competing with, and taking sales away from the non-infringing generics, not AstraZeneca (SUF ¶ 26); (5) AstraZeneca's bargaining position during a hypothetical non-exclusive license negotiation would have been substantially weakened as its sales were rapidly declining due to prior generic entry (Ex. 62 (Excerpts from Expert Report of Philip Green) at 14, 21); (6) several industry surveys report average royalty rates ranging from 11%-15% as a percentage of net sales for fully developed and launched pharmaceutical products (*see* Ex. 62 at 18-19; Ex. 78 (Excerpts from Licensing Executives Society, BioPharmaceutical Royalty Rates & Deal Terms Report (June 2008)) at 26; Ex. 77 (McCarthy & Bonifant, BioPharma Royalty Rate Survey (Sept. 2011)) at 257; Ex. 79 (Sharon Finch, "Royalty Rates: Current Issues and Trends" *Journal of Commercial Biotechnology* (Winter 2001)) at 224-30); (7) the licenses involved in most industry studies are primarily for exclusive licenses (Ex. 78 at 16); the hypothetical license here was non-exclusive, which would result in a lower royalty rate (Ex. 62 at 19); (8) a 2004 analyst report concluded that, "[g]iven the multiple players in the market and the launch of Prilosec OTC, . . . damages [to AstraZeneca] will be limited if Teva/Impax is ultimately found to infringe (Ex. 62 at 16 n.50; Ex. 76 (Cowen & Co., "Teva Pharmaceutical: Generic Omeprazole Launch is Underway" (Sept. 9, 2004)) at 1); and (9) the 22% royalty rate Teva paid to AstraZeneca in the settlement equates to a royalty of more than [redacted] of the [redacted] million in gross profits Teva earned from its accused infringing sales. *See* SUF ¶ 23.

Plaintiffs' claim should be rejected as a matter of law for the reasons addressed below in Part II. In addition, summary judgment should be entered on Plaintiffs' claim that the Accolate settlement involved a large, unjustified reverse payment because Plaintiffs have no evidence that, if AstraZeneca had not settled with DRL, AstraZeneca would have won the litigation or obtained a damages award that would have exceeded the attorneys' fees saved by the settlement.

At the time of the settlement, DRL had prevailed on summary judgment and the district court had determined that DRL's product did not infringe AstraZeneca's patent. *AstraZeneca UK Ltd. v. Dr. Reddy's Labs., Ltd.*, No. 08-3237 (MLC), 2010 U.S. Dist. LEXIS 120706 (D.N.J. Nov. 15, 2010). Any putative liability of DRL to AstraZeneca in the Accolate Litigation was contingent on DRL (1) losing the pending appeal; (2) losing on remand in the district court, resulting in a damages award against it; and (3) losing any appeal after remand. Plaintiffs have no competent evidence that all of these events would have transpired if the parties had not settled, nor do Plaintiffs offer any evidence of the size of the contingent liability that DRL faced—much less the supposed value that AstraZeneca transferred to DRL by settling the Accolate litigation without requiring DRL to pay AstraZeneca a sum of money. Plaintiffs therefore have no evidence that the Accolate settlement was a reverse payment at all, much less that it was a large, unjustified reverse payment—or even a payment that exceeds the attorneys' fees that AstraZeneca avoided by settling.

The Retailer Plaintiffs have proffered that expert witness Professor John R. Thomas will opine that "AstraZeneca had a substantial basis for prevailing on appeal" and a "significant chance of overturning the district court's opinion on appeal in the Accolate Litigation. SUF ¶ 39. Setting aside the question whether Professor Thomas' legal opinion concerning the likelihood of reversal on appeal is admissible, he makes no attempt to quantify the value of AstraZeneca's

claims in the Accolate litigation—in other words, he offers no opinion on the supposed value that AstraZeneca paid to DRL through the Accolate settlement. *Id.*[13]

The Class Plaintiffs' proffered expert, Shashank Upadhye, offers the entirely conclusory opinion that, because of the Accolate settlement, "[DRL's] product was no longer potentially subject to patent damages." SUF ¶ 40. Mr. Upadhye makes no attempt to analyze the merits of AstraZeneca's claims in the Accolate litigation, the likely outcome of that litigation absent a settlement, or the size of any damages claim that AstraZeneca could have advanced or won in that case. He offers no opinion regarding the dollar value of the supposed payment made by AstraZeneca to DRL through the Accolate settlement. *Id.* Indeed, Mr. Upadhye admitted in his deposition that he performed *no analysis whatsoever of the Accolate litigation*. *Id.*[14]

Finally, Class Plaintiffs' expert Professor Thomas McGuire offers the conclusory opinion that the Accolate settlement "constitutes a 'payment' to DRL." SUF ¶ 41. As he admitted in his deposition, he makes no attempt to quantify this alleged payment. *Id.* Nor does he attempt to address the merits of AstraZeneca's claims in the Accolate Litigation or the likely outcome of that litigation absent a settlement. He admits that he did not review any documents from the

[13] Professor Thomas offers no opinion on the likely outcome of a trial on remand or the amount of damages AstraZeneca might have won on remand. SUF ¶ 39.

[14] In his deposition, Mr. Upadhye stated "I'm not here to discuss or opining on the quality or the merits of the Accolate litigation." SUF ¶ 40. He performed no analysis of the probability of AstraZeneca winning on appeal (*id.*) or of whether AstraZeneca would have prevailed on remand if it had won its appeal (*id.*). Nor did Mr. Upadhye perform any analysis of the value or merits of DRL's claim against AstraZeneca for attorney's fees, which DRL released as part of the settlement (*id.*); or any analysis of what it would have cost AstraZeneca to litigate the case to conclusion (*id.*).

Accolate litigation and has no opinion concerning the merits of that litigation or its likely outcome. *Id.*[15]

At the summary judgment stage, Plaintiffs cannot rely on wholly conclusory allegations and speculation that the Accolate Settlement involved a "payment" because AstraZeneca purportedly forgave DRL's "outstanding infringement liability." *See Medina-Rivera v. MVM, Inc.*, 713 F.3d 132, 136 (1st Cir. 2013) (plaintiff "cannot rely on speculation to avoid summary judgment"); *Hannon v. Beard*, 645 F.3d 45, 48 (1st Cir. 2011) ("Conclusory allegations and rank speculation . . . will not suffice to defeat a properly supported summary judgment motion."), *cert. denied*, 132 S. Ct. 1105 (2012); *Mid-State Fertilizer Co. v. Exch. Nat'l Bank*, 877 F.2d 1333, 1338-40 (7th Cir. 1989) (affirming grant of summary judgment to defendant where plaintiff's expert "presented nothing but conclusions"). Plaintiffs have no admissible evidence that quantifies the amount of any judgment that AstraZeneca purportedly would have won against DRL if AstraZeneca had won on appeal, won on remand, and prevailed in a second appeal from a final judgment. Under these circumstances, Plaintiffs have no viable claim that AstraZeneca's settlement of the Accolate litigation involved a "payment" to DRL, let alone a "large, unjustified" payment.

Furthermore, Plaintiffs disregard the fact that the Accolate settlement included a release by DRL of its claims against AstraZeneca. DRL sought attorneys' fees and costs against

[15] Retailer Plaintiffs' expert Keith Leffler's report contains the entirely conclusory opinion that the settlement with DRL involved an "effective payment" "in the form of forgiveness of potential liability." SUF ¶ 42. At deposition, however, Dr. Leffler testified that he is not offering any opinion that the settlement involved an effective payment. *Id.* None of Plaintiffs' purported experts attempts to quantify the value of the alleged payment made to DRL, much less compare it to the attorneys' fees that were avoided in both the Accolate and Nexium patent cases by these settlements. Defendants have filed *Daubert* motions concerning the conclusory and inadmissible opinions of Plaintiffs' experts concerning both the Accolate and Prilosec settlements.

AstraZeneca in the Accolate litigation. SUF ¶ 33. Prior to the settlement, the district court had granted DRL's motion to extend the time for presenting its motion for fees until after the resolution of AstraZeneca's appeal. *Id.* If AstraZeneca had lost the appeal, there was a risk that AstraZeneca would face a claim for attorneys' fees incurred by DRL in the district court and the court of appeals. *Id.* At the time of the settlement, DRL's attorneys' fees were [redacted]. *Id.* Any analysis of whether the Accolate settlement involved a "large, unjustified" payment by AstraZeneca to DRL would need to take into account the fact that the settlement released AstraZeneca from its potential liability to DRL for substantial attorneys' fees and costs and thereby forgave AstraZeneca's contingent liability to DRL. *See* SUF ¶ 35. Yet Plaintiffs' experts did not even consider this point.

In sum, Plaintiffs' claim that the Accolate settlement involved a "large, unjustified reverse payment" to DRL has no factual foundation and is based on rank speculation. Plaintiffs have no evidence that, in the absence of the settlement, AstraZeneca would have won on appeal, won a trial on remand, won in a second appeal from a final judgment, and obtained a judgment against DRL in excess of the legal costs it saved by settling.[16] Nor do Plaintiffs have any evidence that the potential benefit to AstraZeneca of continuing the Accolate litigation outweighed the risk of its exposure to DRL for attorneys' fees arising from the litigation. Without any evidence of the purported value that AstraZeneca transferred to DRL as part of the

[16] AstraZeneca saved approximately $500,000 in litigation costs by dismissing its appeal prior to briefing. SUF ¶ 36. Even if AstraZeneca were able to prevail on appeal (a claim that rests on pure speculation), AstraZeneca would have incurred millions of dollars in attorneys' fees on remand in the district court. *Id.* At the time the district court granted summary judgment against AstraZeneca, fact discovery had not concluded, expert discovery had not begun, and the court had not conducted a claim construction hearing. *Id.*

Accolate settlement, the Court should grant summary judgment as to all claims arising from AstraZeneca's settlements with DRL.

II. ASTRAZENECA'S SETTLEMENTS WITH TEVA AND DRL DID NOT INVOLVE A REVERSE PAYMENT UNDER *ACTAVIS* AS A MATTER OF LAW.

The Court also should grant summary judgment on all claims arising from AstraZeneca's settlements with Teva and DRL because they do not involve reverse payment as a matter of law.

In *Actavis*, the Supreme Court clearly distinguished between reverse payment settlements—which are "unusual," 133 S. Ct. at 2231, and may raise concerns under the antitrust laws—and traditional settlements, which cannot form the basis for an antitrust claim. The Court expressly distinguished between reverse payment settlements—those in which the "settlement requires the patentee [plaintiff] to pay the alleged infringer [defendant]," *id.* at 2227—and traditional settlements in which the defendant pays the plaintiff a compromise sum:

> [W]hen Company A sues Company B for patent infringement and demands, say, $100 million in damages, it is not uncommon for B (the defendant) to pay A (the plaintiff) some amount less than the full demand as part of the settlement—$40 million, for example. . . . *Insofar as the dissent urges that settlements taking these commonplace forms have not been thought for that reason alone subject to antitrust liability, we agree, and do not intend to alter that understanding*.

Id. at 2233 (emphasis added) (citations omitted). The Court emphasized that in such traditional settlements, "a party with a claim (or counterclaim) for damages receives a sum equal to or less than the value of its claim." *Id.* Conversely, in a reverse payment settlement, "a party with no claim for damages . . . walks away with money simply so it will stay away from the patentee's market. That, we think, is something *quite different*." *Id.* (emphasis added).

The FTC similarly made clear in its briefing in the Supreme Court that it was not challenging traditional settlement agreements in which the defendant pays the plaintiff a compromise amount lower than the plaintiff's damages claim:

> Respondents place particular emphasis on the supposed implications of the government's position for ordinary settlement of traditional patent-infringement suits. In such settlements, that patentee accepts a lower amount of damages for alleged past infringement than it might have been awarded in litigation, and the accused infringer accedes to the patent. Respondents assert that this forgiveness of alleged accrued damages is a "payment" no different from the cash payment from a patentee to accused infringer in a reverse-payment agreement.
>
> Respondents' analogy is flawed. When the plaintiff in a suit for monetary relief forgoes a portion of its claimed damages, it provides the defendant part (though not all) of the benefit the defendant would have realized by winning the lawsuit. . . . [T]he compromise result falls where one would naturally expect it—between the dispositions that could result from litigated judgments in favor of the plaintiff and defendant respectively.

Reply Brief for the Petitioner, *FTC v. Actavis, Inc.*, 2013 WL 1099171, at *10-11 (U.S. 2013) (citations omitted).

The FTC described a settlement in which the defendant agrees to settle a $1 million damages claim by paying the plaintiff $500,000 as "routine." *Id.* at *11 n.3. In contrast, a settlement in which the plaintiff agrees to pay the defendant $500,000 "would be extraordinary." *Id.* The FTC made clear that it was challenging only the latter type of "extraordinary" agreement, not the former "routine" agreement. *See id*.

The Supreme Court expressly recognized in *Actavis* that any traditional settlement of patent litigation in which the plaintiff settles for less than the full amount of its damages claim could be construed as including an "implicit net payment from A to B" in the amount of the "settlement discount." 133 S. Ct. at 2233 (quotations omitted). Similarly, such traditional settlements could be construed as conferring value on the defendant because the plaintiff forgives a portion of the defendant's contingent liability by accepting a compromise settlement amount. In any such settlement, the argument could be made that the plaintiff made a "reverse payment" because it accepted an amount lower than it could have received if it had prevailed in the litigation. But the Supreme Court made clear that such traditional settlements are *not* reverse

payment settlements and do not give rise to potential antitrust liability. *Id.*[17] *Actavis* thus rejects, as a matter of law, Plaintiffs' contention that AstraZeneca's compromises of its claims against Teva and DRL in the Prilosec and Accolate cases could constitute reverse payments.

Actavis also approved of patent litigation settlements in which the parties agree on an early entry date for the generic without a payment from the patent-holder to the generic. 133 S. Ct. at 2234, 2237. A settlement that combines both of the features approved by the Supreme Court—an early entry date for the generic and a payment from the generic defendant to the plaintiff patent-holder—cannot raise antitrust concerns, because it would not involve a payment from the patent-holder to the defendant to stay out of the market.

A. The Teva Settlements.

In AstraZeneca's settlement with Teva of the Nexium litigation, Teva obtained the right to sell Nexium beginning on May 27, 2014 (or earlier), five years before the expiration of certain of the Nexium patents asserted against Teva. SUF ¶ 3; *see also* Dkt. No. 131 ¶¶ 72-73 (citing fourteen Nexium patents listed in FDA's Orange Book). That agreement is an early entry agreement specifically approved by the Supreme Court in *Actavis*. *See* 133 S. Ct. at 2234, 2237.

The Teva Nexium settlement did not provide for any payment from AstraZeneca to Teva. SUF ¶ 4. As discussed above, Plaintiffs contend that AstraZeneca made a reverse payment to Teva by virtue of its settlement with Teva in the Prilosec Litigation. But Plaintiffs' theory that the Prilosec settlement—a traditional litigation settlement in which *Teva paid AstraZeneca* [redacted]—could constitute a "reverse payment" in violation of the antitrust laws cannot be reconciled with the Supreme Court's decision in *Actavis*. The Court expressly rejected the

[17] Similarly, the FTC made clear in its briefing in the Supreme Court that, although "routine" settlement agreements could be characterized as providing "consideration" to the defendant in the form of a compromise of the plaintiff's damages claim, they are not actionable under the antitrust laws. Reply Brief for the Petitioner, *FTC v. Actavis*, 2013 WL 1099171, at *10-11 n.3.

argument that a conventional compromise of a damages claim, in which the defendant pays "some amount less than the full demand as part of the settlement," 133 S. Ct. at 2233, could constitute a reverse payment.

Indeed, if AstraZeneca had settled with Teva in the Nexium litigation for a [redacted] payment from Teva to AstraZeneca, that settlement could not be challenged under *Actavis* because it is a traditional, commonplace form of settlement. The fact that the [redacted] payment by Teva here resulted from the settlement of other litigation does nothing to transform a traditional settlement involving a compromise of a damages claim and a payment from the defendant to the plaintiff into a reverse payment settlement.

B. The DRL Settlements.

In AstraZeneca's settlement with DRL of the Nexium litigation, DRL obtained the right to sell Nexium beginning on May 27, 2014 (if not before). SUF ¶ 28. The agreement provides for generic entry five years before certain of AstraZeneca's patents expire, SUF ¶ 29; *see also* Dkt. No. 131 ¶¶ 72-73 (citing fourteen Nexium patents listed in FDA's Orange Book), and is an early-entry agreement specifically approved by the Supreme Court in *Actavis*. *See* 133 S. Ct. at 2234, 2237.

The DRL Nexium settlement does not provide for any reverse payment from AstraZeneca to DRL. SUF ¶ 30. As discussed above, Plaintiffs contend that AstraZeneca made a reverse payment to DRL by virtue of its settlement with DRL in the Accolate Litigation. But the Accolate Settlement was a traditional litigation settlement. By entering into the settlement, AstraZeneca dismissed its appeal from an adverse summary judgment decision, saved the cost of further litigation, and obtained a release from DRL of all claims, including DRL's claim against AstraZeneca for attorneys' fees and expenses. SUF ¶¶ 35-36. AstraZeneca did not agree to make any payment to DRL. SUF ¶ 35. The Supreme Court made clear in *Actavis* that traditional

litigation settlements such as the Accolate settlement are not reverse payment settlements and do not give rise to potential antitrust liability. 133 S. Ct. at 2233.

Plaintiffs seek to re-litigate the Accolate litigation in an effort to make a showing that AstraZeneca could have turned the tide and ultimately won the case if it had not settled. The Court should not permit this diversion. If Plaintiffs' interpretation of the term "reverse payment" were correct, any traditional patent litigation settlement could be challenged and second-guessed under the antitrust laws on the ground that it involved a "reverse payment" because the plaintiff could have done better if it had litigated the case to conclusion. The Supreme Court rejected precisely that argument in *Actavis*. *See* 133 S. Ct. at 2233; *see also Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) ("*[A]ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements.") (emphasis in original).

Nor does the fact that the Accolate settlement was executed at the same time as the DRL Nexium settlement somehow convert the Accolate settlement from a traditional settlement into a reverse payment. This was a conventional litigation compromise in which AstraZeneca gave up a potential claim following an adverse summary judgment decision and DRL gave up its claim against AstraZeneca for attorneys' fees. Under *Actavis*, the terms of the Accolate settlement are immune from antitrust scrutiny. If that traditional settlement could somehow be transformed into a "reverse payment" under the theory that it constituted consideration for the DRL Nexium settlement, then the clear distinction the Supreme Court drew between traditional settlements and reverse payment settlements in *Actavis* would be rendered a nullity.

Indeed, if the DRL Nexium settlement had incorporated all of the terms of the Accolate Settlement, it would not be actionable under *Actavis* because it did not require any payment from AstraZeneca to DRL. The fact that the two settlements are separate agreements does nothing to change the analysis.

CONCLUSION

For the reasons set forth above, the Court should grant summary judgment for AstraZeneca on all claims arising from AstraZeneca's settlements with Teva and DRL.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, James H. Weingarten, hereby certify that this document was electronically filed and served using the Court's ECF system on December 10, 2013.

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